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SUMMARY OF SAFETY AND EFFECTIVENESS

Sponsor: Biomet, Inc.

Manufacturer: Biomet Manufacturing Corp.
56 East Bell Drive
Warsaw, Indiana 46582

Proprietary Name: AVL Hinge Knee System

Common or Usual Name: hinge knee system

Classification Name: knee joint femorotibial metal/polymer constrained cemented prosthesis (CFR 888.3510)

Device Classification: Class II

Device Product Code: 87 KRO

Device Description: The AVL is composed of two components linked together to limit movement in all but the sagittal plane. A modular femoral component is joined to a modular tibial component by means of a yoke and axle. The design is based upon the features of the Finn Knee System (K945018). The modification was the addition of an anti-sublux mechanism.

The yoke of the AVL Hinge Knee fits into a cavity of the tibial component and is cushioned by polyethylene bushings. This assembly provides limited rotation of the knee. The yoke fits through the underside of the polyethylene tibial bearing insert for attachment to the femoral component between the condyles. Inserts are available in three thicknesses. A locking ring is inserted over the tibial bushings which prevents the yoke from pulling out of the tibial tray. The addition of the locking ring forms the anti-sublux mechanism.

The tibial and femoral components are joined by inserting the axle from one side of the femoral component, through the yoke to the other side of the femoral component. A locking pin is placed in the yoke, away from the articulating surface, to secure the system. Polyethylene femoral bushings cushion the axle in the femoral condyles.

Indications for Use: The AVL Hinge Knee System is indicated for painful and disable knee joint resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis where one or more compartments are involved; correction or varus, valgus, or posttraumatic deformity; corrections or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure; ligament deficiencies; and tumor resection. All components of the system are intended for use with bone cement.

Potential Risks: The potential risks associated with this device are the same as with any joint replacement device. These include, but are not limited to:

Reaction to bone cement	Blood vessel damage	Bone fracture
Deformity of the joint	Soft tissue imbalance	Infection
Cardiovascular disease	Delayed wound healing	Hematoma
Fracture of the cement	Metal sensitivity	Dislocation
Implant loosening/migration	Fracture of the components	Excessive Wear
Tissue growth failure	Nerve damage	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 3 2001

Ms. Michelle L. McKinley
Regulatory Specialist
Biomet, Inc.
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K010774
Trade Name: AVL Hinge Knee System
Regulatory Class: II
Product Code: KRO
Dated: January 17, 2001
Received: March 14, 2001

Dear Ms. McKinley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010774

Device Name: AVL Hinge Knee System

Indications for Use:

The AVL Hinge Knee is indicated for:

1. Painful and disable knee joint resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis where one or more compartments are involved.
2. Correction of varus, valgus, or posttraumatic deformity.
3. Correction or revision of unsuccessful osteotomy, arthtrodesis, or failure of previous joint replacement procedures.
4. Ligament deficiencies
5. Tumor resection

All components of the system are intended for use with bone cement.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE OF ANOTHER PAGE IS NEEDED)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010774